

Occupational Knowledge International

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Ms. Jennie Butler
Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

July 20, 2000

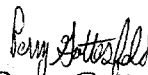
Re: Petition 00P-1210/ item code ZP1 to Restrict Sale of Coal Tar-Containing Products

Dear Ms. Butler,

The European Union Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers has just recently completed a review of the use of "refined" coal tar in "hair care rinse off products" such as shampoos. I have attached a list of the Committee members. The most recent opinion as well as the Committee's 1996 opinion on the same topic are also attached for distribution for FDA to consider.

Please contact me if you have any questions at (415) 441-5199.

Sincerely,


Perry Gottesfeld, M.P.H.
Executive Director

00P-1210

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OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD
PRODUCTS INTENDED FOR CONSUMERS

CONCERNING

REFINED COAL TAR BY BI-DISTILLATION

adopted by the SCCNFP during the 13th Plenary meeting of
of 28 June 2000

Executive Summary

1. General data

- 1.1 Identity of the ingredient : Refined Coal Tar by Bi-distillation. Maximum benzo(a)pyrene content: 0.1 ppm, total of the following polyaromatic derivatives: benz(a)anthracene, chrysene, benzo(k)fluoranthene, benzo(j)fluoranthene, dibenz(a,h)anthracene, indeno(1,2,3-cd)pyrene and benzo(b)fluoranthene must not exceed 1 ppm
- 1.2 CAS n° : not available
- 1.3 Use (applied for) : cosmetic ingredient at the level of maximum 5% in hair care rinse-off products

2. Terms of reference

2.1 Context of the question

The adaptation to technical progress of the Annexes to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

Request to change Annex II, to Council Directive 76/768/EEC. Modify n° 420: Crude and refined tars with the exception of Refined Coal Tar by Bi-distillation listed in the annex III, part I, n°.

2.2 Request to the SCCNFP

The SCCNFP is requested to answer the following questions:

- * Can refined coal tar by bi-distillation be removed from Annex II listing?
- * Can refined coal tar by bi-distillation with the following specification of the raw materials:
 - maximum benzo(a)pyrene content: 0.1 ppm
 - total of the following polyaromatic derivatives: benz(a)anthracene, chrysene, benzo(k)fluoranthene, benzo(j)fluoranthene, dibenz(a,h)anthracene, indeno(1,2,3-cd)pyrene and benzo(b)fluoranthene must not exceed 1 ppm

be present at a maximum concentration of 5% in rinse-off products only, not applied to the mucus membrane, be used safely?

3. Safety Assessment & Classification

The assessment followed the Notes of Guidance under scientifically based premises of consumer safety and leads to a classification 2A for the intended use.

Evaluation and opinion on : Refined Coal Tar by Bi-distillation

Evaluation of genotoxicity, (*in vitro/ in vivo*) and carcinogenicity have shown that the compound cannot be safely used under the conditions stated in the Opinion.

4. Opinion

Refined coal tar by bi-distillation should not be removed from the Annex II listing. Refined coal tar by bi-distillation present at a maximum concentration of 5% in rinse-off products cannot be used safely as it contains polycyclic aromatic hydrocarbons which are genotoxic carcinogens and it may represent an unacceptable high risk of skin cancer.

5. Statement on the toxicological evaluation

The SCCNFP is the scientific advisory body to the European Commission in matters of consumer protection with respect to cosmetics and non-food products intended for consumers.

The Commission's general policy regarding research on animals supports the development of alternative methods to replace or to reduce animal testing when possible. In this context, the SCCNFP has a specific working group on alternatives to animal testing which, in co-operation with other Commission services such as ECVAM (European Centre for Validation of Alternative Methods), evaluates these methods.

The extend to which these validated methods are applicable to cosmetic products and its ingredients is a matter of the SCCNFP.

SCCNFP opinions include evaluations of experiments using laboratory animals; such tests are conducted in accordance with all legal provisions and preferably under chemical law regulations. Only in cases where no alternative method is available will such tests be evaluated and the resulting data accepted, in order to meet the fundamental requirements of the protection of consumer health.

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Europa

The European
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Food
Safety



Food Safety :
from the Farm to the Fork

[Scientific Committees](#) [Scientific Committee for Cosmetic Products, and Non-Food Products intended for Consumers](#)

Members



The members of the Scientific Committees listed hereunder can be contacted through the Secretariat of each Committee, whose whereabouts figure on this page.

Alphabetical list of the scientists appointed by the Commission as members of the Scientific Committee set up by Decision 97/579/EC of 23 July 1997.

Prof. Dr. med. Andersen, Klaus E.

Professor of Dermatology, Odense University Hospital, Institute of Clinical Research Dermatology & Venereology, Department of Dermatology, Denmark

Prof. Anton, Robert

Professeur de Pharmacognosie, Université Louis Pasteur, Strasbourg, Faculté de Pharmacie, Laboratoire de Pharmacognosie, France

Dr. Doré, Jean-François A.T.

Directeur de Recherche, INSERM, Biologie des Gènes Suppresseurs de Tumeurs, Unité 453 - Bâtiment Le Cheney - Centre L. Bérard, France

Prof. Dr. Elsner, Peter

Direktor, Klinik für Hautkrankheiten der Friedrich-Schiller-Universität, Deutschland

Glomot, Rémi

Expert toxicologue, Paris, France

Prof. Kapoulas, Vassilios M.

Emeritus Professor of Biochemistry, Greece

Prof. Dr. Kemper, Fritz H.

Professor emeritus für Pharmakologie und Toxikologie, Universität
Münster, Deutschland - *President of the Committee*

Drs. Lina, Berend A.R.

Toxicologist; Study director; Division Quality Consultant, TNO, Nutrition
and Food Research Institute, Toxicology Division, Department of
General Toxicology, Netherlands

Prof. Loprieno, Nicola

Full Professor, University of Pisa, Faculty of Science, Laboratory of
Genetic Toxicology, Italia

Prof. O'Mahony, D.P.

Professor emeritus of Pharmacology and Therapeutics, University
College Cork, Ireland

Prof. Parra Juez, José

Research professor, Consejo Superior de Investigaciones Científicas
(CSIC), Centro de Investigación y Desarrollo, Surfactants, ESPANA

Prof. Dr. Rogiers, Vera M.

Professor, Vrije Universiteit Brussel, Faculty of Medicine and
Pharmacy, Department of Toxicology, Belgique

Prof. Sanner, Tore

Professor, The Norwegian Radium Hospital, Institute for Cancer
Research, Department for Environmental and Occupational Cancer,
Norway

Dr. Vives Rego, Josep

Universidad de Barcelona, Facultad de Biología, Departament de
Microbiología, España

Dr. White, Ian R.

Director; consultant dermatologist, St. Thomas' Hospital, St. John's
Institute of Dermatology, Department of Contact Dermatitis and
Environmental Dermatoses, United Kingdom

Environmental Dermatoses, United Kingdom

Contact

Antoon Van Elst
Secretary of the Scientific Committee on Cosmetic and Non-Food
Products
European Commission
Health & Consumer Protection DG
Directorate B - Scientific Opinions on Health Matters
Unit B2 : Management of scientific committees I
Rue Belliard 232, Office n° B232 6/59
☎ Tel. : +32 2 29 90433
☎ Fax : +32 2 29 57332
✉ E-mail : Antoon.van-elst@cec.eu.int

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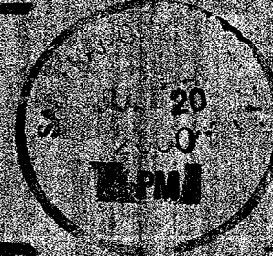
SEARCH

INFORMATION

FEEDBACK

Scientific Committees Scientific Committee for Cosmetic Products, and Non-Food Products intended for Consumers
FOOD SAFETY | PUBLIC HEALTH | CONSUMER PROTECTION | DIRECTORATE GENERAL "HEALTH & CONSUMER PROTECTION"

OCCUPATIONAL KNOWLEDGE
1255 Post Street #437
San Francisco CA 94109



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